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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,248	10/16/2001	Mark A. Hoffman	CRNI.83071	6008

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/981,248	HOFFMAN ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/28/2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-30,55-60,85-89,91 and 92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-30,55-60,85-89,91 and 92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/2008 has been entered.

Applicant's arguments, filed 10/28/2008, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 10/28/2008, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant's cancellation of claim 90 in the response filed 10/28/2008 is acknowledged.

Applicant has newly added claim 92 in the response filed 10/28/2008, which has been acknowledged and entered.

Claims 25-30, 55-60, 85-89, and 91-92 are the current claims hereby under examination.

The following rejection has been necessitated by amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-30, 55-60, 85-89, and 92 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 25, 55, 85, and 92 (and all claims dependent therefrom) comprise the amended claim wording “publishing a graphical user interface,” wherein support for said publishing has not been found in the instant specification. Applicant points to paragraphs [0033] and [0039] – [0042] of the published application for support, wherein functionality of such a GUI is discussed, but not with regards to publishing. Therefore, said publishing has been deemed as new matter.

Claim 85 comprises the unsupported amended claim wording of “automatically providing a notification in an email addressed to a physician that informs the physician to no longer administer the agent, wherein the physician is identified by the person’s electronic medical record,” which has been deemed as new matter. The only reference of an email message is found in paragraph [0052] with regards to emailing a physician that a particular mutation has not been found and that "current test results do not indicate a high risk of this phenotype." There is not support for an email message

indicating not to administer a particular agent, nor identifying the physician by the person's electronic medical record.

The following rejection has been necessitated by amendment:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-30, 85-89, and 91-92 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Claims 25-30 and 91-92 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental

steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

Claims 85-89 are drawn to a computer program on computer readable media. A review of the specification does not show a definition of computer readable media such that excludes an embodiment that is information in a signal. For example, paragraph [0026] of the published application recites computer media as comprising communication media, wherein the communication media comprises wireless communication, i.e. a carrier wave. As such an embodiment of the claims read on non-statutory subject matter (In re Nuijten 84 USPQ2d 1495 (2007)).

Response to Arguments:

Applicant's arguments filed 10/28/2008 with respect to the rejection of claims 85-89 by the patent board of appeals have been fully considered but they are not persuasive.

Applicant argues that the amendment to include “one or more computer storage media having computer-executable instructions embodied thereon that, when executed, perform a method,” overcomes the rejection.

Applicant’s arguments are not found persuasive as paragraph [0026] of the published application recites computer media as comprising communication media, wherein the communication media comprises wireless communication, i.e. a carrier wave. A carrier wave is capable of carrying, i.e. embodying, such computer-executable instructions. Therefore, claims 85-89 remain drawn to non-statutory subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-30, 55-60, 85-89 and 91-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol. 286, pp. 487-491) and REINHOFF et al. (US 2002/0049772 A1, filed 5/26/2000) and further in view of Fey et al. (US Pub. 2002/0038227, filed 2/26/01).

Claims 25, 55, 85 and 91 are directed to a computer-implemented method for processing hereditary data, and to a computer system and medium comprising instructions or components for performing the method, wherein the method comprises receiving a genetic test result value for a person, querying a computerized table listing polymorphism values and atypical clinical events associated with h polymorphism values, determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents, and outputting an “interpretation” of the genetic test result value and the list of risk-associated agents. Claims 26, 56, 86 and 91 further limit the method to comprise determining if a patient has been exposed to a risk-associated agent. Claims 27, 57, and 87 limit the method to further comprise accessing an electronic medical record. Claims 29-30, 59-60 and 89-90 limit the method to comprise initiating a clinical action if

a patient has been exposed to a risk-associated agent, specifically to inform a clinician to no longer administer the agent.

ICHIKAWA teaches a method for processing hereditary (genetic) data related to response to azathioprine or mercaptopurine (clinical agents) wherein genetic tests results for individual patients are received, the presence of a polymorphism is determined, wherein particular mutations or polymorphisms are associated with atypical clinical events (side effects) of administration of various drugs, and a decision made to change a drug dosage (p. 523). Since drug dosages are based on the genetic testing results in the method of ICHIKAWA, the method necessarily includes a step of outputting the test results and the list of drugs. ICHIKAWA also teaches that one decision based on the results may be discontinuation of drug use (p. 523, left column). ICHIKAWA does not specifically teach querying a computerized table listing polymorphism values and atypical events associated with the polymorphism values, electronic medical records, a computer-implemented method, a computer system or a computer-readable medium.

EVANS teaches association of a variety of drugs with polymorphisms, which are also known to be associated with "idiosyncratic" drug reactions or altered drug sensitivity (p. 489, Table 1), thus teaching a list of "risk-associated agents". EVANS teaches that his Table 1 is a computerized table of atypical clinical events associated with polymorphism values (see the legend for Table 1 which states "A comprehensive listing is available at www.sciencemag.org/feature/data/104449.shl"). It is noted that Table 1 of EVANS includes the drugs and at least one of the polymorphic sites taught

by ICHIKAWA. It is further noted that the table of EVANS contains many of the genes, polymorphic sites, and atypical events disclosed by the instant specification in Table 2 on page 16. EVANS also teaches automated systems to associate an individual's genotype with polymorphic genes in order to optimize drug administration and disease treatment (p. 490, right column). EVANS does not specifically teach accessing an electronic medical record.

REINHOFF teaches a computer-implemented method, and a system and computer-readable medium comprising instructions for performing the method, wherein information with regard to a patient's polymorphic profile is linked to a degree of response of the patient to a treatment, specifically to side effects; i.e. an "atypical" clinical response (paragraphs 33, 38, 57 and 59). Specifically, REINHOFF teaches populating a computerized database with genotypic and phenotypic data (para 38) and teaches that polymorphic profiles of individuals may be associated with response to drugs in a computerized method (para 57). He further teaches analysis of such data in a computerized database (para 58), thus teaching a step of "querying" a computerized listing comprising polymorphic data and atypical clinical events associated with the polymorphic data. REINHOFF also teaches that a variety of electronic medical and/or clinical records may be accessed in his method (paragraph 27).

It would have been obvious to one of ordinary skill in the art at the time of invention to have computerized, or automated, the genetic screening method of ICHIKAWA, as taught by REINHOFF, and to have accessed/queried a computerized list of treatment/drug options, as taught by EVANS, in the automated method of ICHIKAWA

and REINHOFF, where the motivation would have been to facilitate use of the method to identify patients appropriate for treatment when a choice is to be made among various options, as taught by REINHOFF (paragraph 59) and/or to determine an appropriate dosage of the agent, as taught by REINHOFF (paragraph 57) and ICHIKAWA (p. 523, left column, last paragraph).

REINHOFF suggests, but does not explicitly recite a graphical user interface having specific functionality.

REINHOFF suggests this because REINHOFF teaches, at paragraph [0040] computers running customized software supporting the service provided by the taught invention, wherein it is common for software to have built in GUIs for easier functionality for a user. Furthermore, REINHOFF teaches at paragraph [0010] that the computer program product allows identification of a susceptibility locus in individuals using genetic screening methods to assess an individual's risk of certain disease, i.e. it is commonly understood wherein a doctor would perform the risk assessment thereby implying that the networked system comprising the program product is intended not just for patients, but also doctors or hospitals.

Fey et al. teach at paragraphs [0022] [0048] and [0055] an application of health data management which involves a graphical user interface written for web browser applications wherein the user has a unique identification and may enter information through the GUI. Fey et al. at paragraph [0012] teach keeping secure health records, which are accessible by authorized health persons. Fey et al. further teach that custom reports are generated at the time tests are performed that explains the results. Fey et

al. teach at paragraph [0022] wherein results are prepared for the individual and physician. Fey et al. teach at paragraph [0047] wherein the health data may be used by doctors. In addition, Fey et al. at paragraphs [0053] – [0059] and [0063] – [0075] teach a system comprising a means, i.e. a displaying component and computer storage media configured for displaying a graphical user interface as in claims 55 and 85. With further regards to claim 85, Fey et al. teach at paragraph [0031] storing the genetic test results.

Fey et al. does not explicitly teach a GUI that is configured to solicit input from a clinician to ascertain whether to authorize performing a genetic test on a patient. In fact, Fey et al. teach, i.e. paragraph [0057] that the invention is directed to enabling a client/consumer to order genetic testing without doctor's approval. Furthermore, Fey et al. teach that a client can use the taught invention to determine genetic risk towards disease or conditions or discover genetic predispositions.

Although it appears that the invention of Fey et al. may be directed away from a physician based system, it is the functionality of said system, which is taught that is the focus. The invention taught by Fey et al. has the functionality of using a graphical user interface to solicit input, albeit a client, to ascertain whether to perform a genetic test, displays identification of the genetic test to be performed, receives approval or authorization from the client to carry out the genetic test, ensures identification of the person, and is configured to receive result value of the genetic test for the person.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the system for authorizing genetic tests and displaying results, etc. as taught by Fey et al. for use by a physician as taught by REINHOFF.

This is because REINHOFF teaches a program product for studying genetic data and using genetic screening methods to assess increased risk of certain diseases and conduct basic research on population genetics. It would have been obvious to the skilled artisan to improve the invention of REINHOFF by adding a secured health data management system, wherein a physician can ascertain whether to authorize performing a genetic test on a patient based on their assessed risk for a certain disease. REINHOFF teaches at paragraphs [0008] – [0009] using a web system to create polymorphic profiles for individuals. Therefore, creating a secured health data management system wherein the polymorphic profiles are stored and further genetic tests can be authorized as deemed necessary can be seen as an improvement wherein the results would be predictable. Moreover, a skilled artisan would find that the differences between the claimed invention and the prior art were encompassed in known variations or in a principal known in the prior art.

Fey et al. does not explicitly teach automatically scheduling counseling for the person, automatically ordering follow-up tests, nor automatically providing a notification in an email address to a physician that informs the physician to no longer administer the agent, wherein the physician is identified by the person's electronic medical record.

However, Fey et al. teach at paragraph [0042] generating custom reports of the genetic tests. Fey et al. further teach at paragraph [0044] the data is analyzed in conjunction with known medical data, such as disease, risk factors, screening factors, etc. Fey et al. at paragraph [0045] teach that the personalized health record reviews

health risks and thoroughly explains test results with follow-up recommendations and determine further health risks.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have automated particular follow-up recommendations such as ordering another genetic test based on a health record or sending an email message to discontinue the administration of a particular drug with known adverse effects on the client with a particular genetic predisposition. This is because the goal of the health data management system is to enable a consumer/client to better monitor their health at a genetic level and monitor their potential health risks based on genetic screening. Therefore, an automated result to a physician indicating an adverse effect of a particular drug being taken would be seen as an obvious improvement to the health management system where the results would have been predictable to one of ordinary skill in the art. Furthermore, automation of known methods, such as further automating the automated follow-up recommendations would be recognized as part of the ordinary capabilities of one skilled in the art.

Fey et al. does not explicitly teach ascertaining whether to automatically generate a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents as in claim 91.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have have ascertained a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents. when generating the follow-up recommendations as taught by Fey et al.. This is because the goal of the health data management system is to enable a consumer/client to better monitor their health at a genetic level and monitor their potential health risks based on genetic screening. Therefore, an automated result ascertaining a low-risk or high-risk clinical response based on whether the person has been exposed to an agent on a list of risk-associated agents; if the person has been exposed, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents, when generating the follow-up recommendations as taught by Fey et al. would be seen as an obvious improvement to the health management system where the results would have been predictable to one of ordinary skill in the art. Furthermore, automation of known methods, such as further automating the automated follow-up recommendations would be recognized as part of the ordinary capabilities of one skilled in the art.

Fey et al. teach at paragraphs [0019] and [0049] that the medical records are accessible and updating the healthcare system, wherein updating integrates heredity data with newfound knowledge as in claim 86.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin/
Primary Examiner, Art Unit 1631